UTAH VACCINES FOR CHILDREN (VFC) PROGRAM PROVIDER MANUAL

UTAH DEPARTMENT OF HEALTH

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Utah Vaccines for Children Program Provider Operations Manual

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GENERAL INFORMATION

1-1 Utah Vaccines for Children Program Provider Operations Manual

As defined by the Centers for Disease Control and Prevention (CDC), the Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay. In Utah, the program is administered by the Department of Health, Division of Disease Control and Prevention, Bureau of Epidemiology, Immunization Program. This Provider Operations Manual contains the policies and procedures required to enroll and maintain compliance as a VFC provider, and consists of the following four sections:

- General Information
- Program Overview and Compliance Requirements
- Vaccine Ordering and Inventory Management
- Additional Resources

1-1.1 Manual Maintenance

The Utah VFC Program makes every attempt to ensure that the information within this manual is consistently up-to-date. Changes to the manual are reported via the Utah VFC Program list serv, on the Utah Immunization Program website, and in quarterly regional coalition newsletters.

1-2 Contact Information

Following is a list of contact information for the Utah Immunization Program and Utah VFC Program. Business hours for the program are 8:00 AM to 5:00 PM, Monday through Friday.

Internet

The official website for the Utah Immunization Program is located at: http://www.immunize.utah.gov.

Telephone

General Program Line.....801-538-9450
Toll Free Immunization Hotline 1-800-275-0659
Fax.....801-538-9440
Email.....immunize@utah.gov

Mailing Address:

Utah Department of Health
Immunization Program
PO Box 142012
Salt Lake City, Utah 84114-2012

Immunization Quality Improvement for Providers (IQIP) representatives

There are two IQIP representatives within the Utah Immunization Program. They will act as a liaison between the clinic and the Utah Immunization IQIP Program (see Section 2-2.4 for more information about IQIP).

Contact information for each IQIP representative is as follows:
Jeni Demeny.....801-538-6837
.....jdemeny@utah.gov
Kayla Rypien 801-538-9048
.....kaylarypien@utah.gov

VFC Provider Relations
Each VFC-enrolled provider is assigned a Provider Relations Representative, who will act as a liaison between the clinic and the VFC Program. To locate the Provider Relations Representative assigned to a specific clinic, please use the official VFC Region map.

Contact information for each Provider Relations Representative is as follows:
Craig Hemingway (Salt Lake County providers M-Z [excluding UofU Clinics], Summit, Wasatch) 385-256-6338
.....chemingway@utah.gov
Jadea Hopes (CHC Inc, Salt Lake County providers A-L, Southwest).....801-657-0249
.....jhopes@utah.gov
Jenny Hubbard-Wood (Utah County, Weber-Morgan, WeeCare Peds).....385-242-6241
.....jhubbard@utah.gov
Liliana Contreras (Bear River, Central, Davis County, Tanner Clinics).....385-242-6644
.....lcontreras@utah.gov
Robert Herrera (Southeast, Tooele, Tri-County, UofU Clinics).....385-235-2742
.....robertherrera@utah.gov

Vaccine Management
The Vaccine Management Team oversees VFC ordering, returns, waste and spoilage, and transfer requests. For questions, please call the Immunization Program line. Inquiries, as well as temperature logs, VOMS training certificates, and other Vaccine Management-related communication may be sent to:

Email.....vacteam@utah.gov

Utah Statewide Immunization Information System (USIIS)
For technical support or enrollment assistance, please contact:

USIIS Support.....801-538-3440
Toll Free Support 1-800-678-3440
Email.....usiistracking@utah.gov

VFC List Serv
The VFC list serv is a private group email list. The Utah VFC Program will periodically send out information regarding the program, including annual documentation and training requirements, new policies, and updates regarding the availability of vaccine. The email addresses added to this

list serv are private and are used solely by the VFC Program to communicate directly with providers.

All Primary and Back-up VFC Coordinators (see Section 2-2.1) are added to the VFC list serv automatically after completing required training. Other staff members may be added upon request.

1-3 Definitions

Following is a list of definitions relevant to the administration, policies, and procedures of the Utah VFC Program:

Administration Fee: The amount a clinic charges a non-Medicaid VFC-eligible child for each vaccine administered. State Medicaid agencies have the authority to reimburse at a lower level. The Centers for Medicare and Medicaid Services (CMS) has the responsibility of setting and adjusting the maximum regional charges (see Section 2-2.6).

Advisory Committee on Immunization Practices (ACIP): The ACIP consists of 15 experts in fields associated with immunization who have been selected by the HHS Secretary to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and CDC on the control of vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations. VFC resolutions passed by the ACIP form the basis for VFC Program policies on vaccine availability and usage. They may not necessarily match the general usage recommendations of the ACIP but rather represent the rules that providers must follow for administering each specific vaccine under the VFC Program.

VFC-ACIP Vaccine Resolutions may be found here.

Centers for Medicare and Medicaid Services (CMS): Agency that provides oversight of the Medicare and Medicaid programs. Funding for VFC Program is allocated through this agency.

Children's Health Insurance Program (CHIP): Authorized under Title XXI of the Social Security Act, jointly financed by the Federal and State governments and administered by the States. The CHIP program provides insurance to children in families with incomes that are above Medicaid eligibility but without access to private insurance. Within broad federal guidelines, each State determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures. In Utah, children who are enrolled in CHIP at the time of service are eligible for VFC vaccine. More information about Utah CHIP may be found here.

Department of Health and Human Services, Office of Inspector General (OIG): Office mandated to protect the integrity of the Department of Health and Human Services (HHS) programs and their beneficiaries. It is generally responsible for identifying, communicating and correcting activities of waste, fraud or abuse within HHS programs.

Family Planning Clinic: Clinic or provider whose main purpose is to prescribe contraceptives. This does not include school-based clinics or any VFC-enrolled provider whose main services are primary or acute care services.

Federally Qualified Health Center (FQHC): Health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide healthcare to a medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service (PHS) Act, as well as "look-alikes," which meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian Health Service centers.

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Fully Insured: Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

Indian (American Indian or Alaska Native): As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).

Insurance: For the purpose of the VFC Program, "insurance" is defined as a plan that is:

- Regulated by a State's Insurance Commissioner and/or
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA). ERISA is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide protection for individuals in these plans.

Immunization Quality Improvement for Providers (IQIP): The purpose of IQIP is to promote and support the implementation of provider-level quality improvement strategies designed to increase vaccine uptake among childhood and adolescent patients in adherence to the ACIP-recommended routine schedule.

Medicaid: Federal and state partnership that creates a medical assistance plan for poor and disabled Americans. It is sometimes called Title XIX because it was authorized under Title XIX of the Social Security Act. VFC is a part of the larger Medicaid program but has different eligibility criteria than the Medicaid assistance plan for both providers and participants. More information about Utah Medicaid can be found here.

Medicaid-Enrolled Child: A child who is currently enrolled in the Medicaid program.

Medicaid Fraud and Control Unit (MFCU): Unit responsible for investigating and prosecuting (or referring for prosecution) violations of all applicable state laws pertaining to fraud in the administration of the Medicaid program, including the VFC Program. In general, MFCUs are located in the Office of the State Attorney General.

Rural Health Clinic (RHC): An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time the clinic is open.

Underinsured Child: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only).

NOTE: In Utah, underinsured children are eligible to received VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). A list of these providers can be found here.

Uninsured Child: A child who has no health insurance coverage.

Utah Immunization Program: The parent program of the Utah VFC Program. It is housed within the Utah Department of Health, Division of Disease Control and Prevention, Bureau of Epidemiology.

Vaccine Management Team: Program within the Utah Immunization Program that performs inventory management for the Utah VFC Program. Vaccine Management oversees all VFC orders, returns, waste, and spoilages.

VFC Abuse: Provider practices that are inconsistent with sound fiscal, business, or medical practices, and that result in an unnecessary cost to the Medicaid program, and/or including actions that result in an unnecessary cost to the Utah Immunization Program, a health insurance company, or a patient; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

VFC-Eligible Child: Child who is 18 years of age or younger and meets one or more of the following categories:

- Is an American Indian (AI) or Alaska Native (AN); or
- Is enrolled in Medicaid; or
- Has no health insurance; or
- Is underinsured and receives vaccine through a FQHC or RHC

PROGRAM OVERVIEW AND COMPLIANCE REQUIREMENTS

2-1 VFC Program Details

The VFC Program is federally funded and administered by the Utah Department of Health, Division of Disease Control and Prevention, Bureau of Epidemiology, Utah Immunization Program. Vaccines are distributed to enrolled providers via the Centers for Disease Control and Prevention (CDC). The goal of the program is to provide physicians and public health clinics with the vaccine stock they need to immunize children who may not otherwise be vaccinated due to an inability to pay. This vaccine is granted free of charge to enrolled providers as long as compliance requirements are maintained.

2-2 Compliance Criteria

In order to remain compliant while participating in the VFC Program, enrolled providers must meet the following requirements:

- Determine a signing physician (must be a practitioner authorized to administer pediatric vaccines under state law – medical license number is required).
- Delegate two staff members as Primary and Back-up VFC Coordinators.
- Submit initial and annual Provider Agreement packets and participate in an enrollment site visit.
- Follow all federal and program policies while administering vaccine, including eligibility screening and IIS documentation.
- Adhere to federal and state storage and handling requirements.
- Participate in all required site visits, including compliance, AFIX, and unannounced storage and handling visits.
- Participate in required training modules.

Further details regarding each requirement may be found below.

2-2.1 Signing Physician, VFC Primary and Back-up Coordinators

Each enrolled provider is required to delegate a signing physician and two staff members as VFC Coordinators that work with VFC Provider Relations Representatives to implement the VFC Program in their clinics. The signing physician is primarily responsible for overseeing VFC Program implementation within the clinic, whereas VFC Coordinators will implement day-to-day VFC operations. The following are responsibilities of the VFC Coordinators:

Primary Coordinator

The Primary Coordinator assumes the lead in VFC Program implementation within the clinic. Responsibilities include:

- Assigning a Back-up Coordinator.
- Familiarity with all requirements of the VFC Program.
- Supervising administration of VFC vaccine.
- Ensuring eligibility standards are consistently evaluated and met at each visit.
- Overseeing all temperature logs and data logging equipment, software, and reports.

- Maintaining emergency response plans and successfully implementing when necessary.
- Participating in all required site visits and training modules.

Back-up Coordinator
The Back-up Coordinator is responsible for assisting the Primary Coordinator in day-to-day VFC Program administration. They are expected to maintain the same level of competency as the Primary Coordinator and should be able to successfully implement all VFC policies and procedures in the Primary Coordinator's absence.

Staff Changes
VFC-enrolled clinics are required to inform the VFC Program if the signing physician or the VFC Coordinator(s) change.

2-2.2 Provider Agreement and Enrollment Visit

Provider Agreement
The Provider Agreement packet must be completed upon enrollment in the VFC Program and then again at the beginning of each calendar year (re-enrollment). Annual recertification packets are emailed through the official VFC list serv in the fourth quarter of each year and are due by January 1.

Note: Providers are not automatically unenrolled due to failure to submit annual recertification but will be placed on vaccine order hold and contacted by their VFC Provider Relations Representative to discuss withdrawal from the program.

The Provider Agreement is located here, and is updated on an annual basis. Providers must always use the most current version of this document.

Enrollment Site Visit
Upon enrollment, all providers must participate in an Enrollment Site Visit, conducted by the clinic's assigned VFC Provider Relations Representative. The Primary Coordinator is required to be present at this visit and it is recommended that the Back-up Coordinator, as well as any additional staff who will be working with VFC vaccine, be present as well. This visit will only be conducted one time per enrollment.

2-2.3 Eligibility and Documentation Requirements

It is a requirement of the program that every child be screened for VFC eligibility at each visit. Children are considered eligible for VFC if they meet the following requirements:

- 18 years of age or younger, AND one of the following:
  - Enrolled in Medicaid
  - Enrolled in Medicaid as a secondary form of insurance
  - Enrolled in CHIP
  - Uninsured (no insurance)
  - Underinsured* (private insurance does not cover certain recommended vaccines or a cap on vaccines exists that prevents patient from receiving all recommended vaccines)

- American Indian
- Alaska Native

*Underinsured patients may only be administered VFC stock at a FQHC/RHC authorized by the CDC to administer VFC vaccine.

NOTE: Patients with private insurance with a high deductible are NOT eligible for VFC vaccine unless they qualify under another category.

Providers enrolled in the VFC Program are required to document eligibility screening for every patient, regardless of the results of the screening.

IIS Documentation
VFC-enrolled providers are required to submit detailed information to the Utah Statewide Immunization Information System (USIIS) regarding all administered doses of vaccines, regardless of patient age or eligibility. This should occur within 14 days of administration. Documentation should include:

- Evidence of eligibility screening (insurance or VFC code or similar)
- Patient age or date of birth
- Address of clinic
- Date of immunization administration
- Name of vaccine administered
- Vaccine Information Statement (VIS) date provided to the patient, AND
- Vaccine Information Statement (VIS) publication date (printed on VIS)
- Vaccine lot number
- Vaccine manufacturer
- Name and title of the person administering the immunization

All documentation requirements must be included for every immunization given by the VFC provider. More information on vaccine documentation requirements under federal statute 42 U.S.C §300aa-25 can be found here.

Prior to a compliance visit, the Provider Relations Representative will conduct a randomized chart review (see Section 2-2.4). All immunizations, including VFC and private, may be reviewed for documentation compliance.

For individual access to USIIS, clinic employees must complete a USIIS User Confidentiality and Security Agreement. Information for submission is located on the form.

Vaccine Information Statements
Vaccine Information Statements (VISs) are information sheets produced by the CDC that explain both the benefits and risks of a vaccine. All providers in the United Stated who administer certain vaccines to any child or adult, shall provide a copy of each applicable VIS prior to administration of each dose. More information on the National Childhood Vaccine Injury Act (federal statute 42 U.S.C. §300aa-26) can be found here.

All vaccines that are supplied by the Utah VFC Program require a VIS. In addition to providing the VIS prior to vaccine administration, the publication date and the date given to the patient must both be documented in the patient chart.

Vaccine Information Statements are updated periodically. During a compliance visit (and occasionally an unannounced visit), the clinic's VFC Provider Relations Representative will audit the VISs to ensure they are kept up to date. Clinics are responsible for maintaining the most recent versions of the VISs. The most current version of each document can be found here.

Borrowing Documentation
The borrowing of VFC to supplement a lack of private stock, or vice versa, is not allowed. If accidental misuse occurs, enrolled providers are required to report this information to the Utah VFC Program (see Section 3-5.5).

Vaccine Management Plan
VFC-enrolled providers must maintain a Vaccine Management Plan that outlines standard operating procedures as well as emergency protocol for overseeing public vaccine stock. The CDC requires that vaccine management plans include the following information:

- Current Primary and Back-up Vaccine Coordinator names and contact information
- Staff responsibilities related to vaccine management
- Proper vaccine storage and handling practices
- Delivery receiving procedures
- Emergency plan of action
- Ordering procedures
- Inventory control procedures
- Handling vaccine loss and waste
- Staff training on vaccine management, storage and handling documentation
- Review date (must be reviewed every 12 months at a minimum)
- Signature of party responsible for content

Providers may use the Utah Immunization Program's vaccine management template.

Doses Administered Reports
The CDC requires VFC providers to account for public vaccine doses administered to patients. This information must be reported to the Utah VFC Program on a quarterly basis. The following due dates apply:

- Quarter 1 (January 1 through March 31): Due April 15th
- Quarter 2 (April 1 through June 30): Due July 15th
- Quarter 3 (July 1 through September 30): Due October 15th
- Quarter 4 (October 1 through December 31): Due January 15th

Doses Administered Reports are recorded and submitted in USIIS (see Section 3-5).

Record Retention
Effective January 1, 2018, all documentation pertaining to VFC must be kept on file for a period of seven years. Applicable documentation includes:

- Eligibility screening results
- Chart documentation
- Billing records
- Vaccine Management Plan
- Temperature logs
- Order documentation
- Thermometer certificates of calibration

2-2.4 Site Visits

Enrolled VFC providers will usually receive at least one site visit per year from a VFC Provider Relations Representative. There are three types of site visits:

- Compliance
- Unannounced Storage and Handling
- Follow-up

Clinics may also receive an IQIP visit with representatives from the Immunization Program

Compliance Site Visits

Compliance site visits are conducted on an annual or bi-annual basis and are always scheduled with the clinic by the VFC Provider Relations Representative prior to the date of the visit. The Primary Vaccine Coordinator must be present, and is encouraged to invite the Back-up Coordinator and any other staff that may benefit to attend. A billing representative must be available in person or via telephone to answer billing-related questions.* It is also beneficial for the clinic manager or signing physician to be available at the conclusion of the visit to discuss the visit summary and follow-up requirements. Compliance visits may take up to three hours provided there are no interruptions.

The goal of each compliance visit is to assess a clinic's implementation of key VFC Program requirements and recommendations as well as provide education and technical assistance support to clinic staff. At the time of the visit, the VFC Provider Relations Representative will ask for the following:

- An available space to work and discuss educational and compliance requirements.
- Access to all VFC-related documentation (including, but not limited to, Vaccine Management Plans, temperature logs, certificates of calibration, and Vaccine Information Statements).
- Access to all units where VFC vaccine is being stored.
- Access to circuit breakers that are connected to VFC storage units (a maintenance person may need to be available to provide access to circuit breakers).
- Access to clinic's EMR/EHR in the case that a chart review cross-reference is needed.
- You Call the Shots training (modules 10 and 16) for VFC contacts (these must be renewed annually, see Section 2-2.5).
- Access to back-up data logger and certificate of calibration.

*If it is not possible to reach billing at the time of the visit, the Primary Coordinator should contact them prior to the visit and find out how billing for VFC vaccine is performed as well as the clinic's VFC administration fee (see Section 2-2.6).

Unannounced Storage and Handling Site Visits
By enrolling in the VFC Program, providers authorize VFC staff to perform unannounced visits to inspect for proper storage and handling procedures. The VFC Provider Relations Representative may visit an enrolled provider at any time during normal business hours and will perform the inspection even if the Primary and Back-up Coordinators are not available.

Unannounced visits usually consist of the Storage and Handling section of the full compliance visit. The Provider Relations Representative will inspect the following:

- Vaccine storage units and VFC stock
- Vaccine Management Plan
- Certificates of calibration
- Temperature logs
- Circuit breaker

It is best that all clinic staff be trained on the locations and protocols of the items above in order to prevent non-compliance in the event that the VFC Coordinators are absent when an unannounced visit occurs.

NOTE: While the Utah VFC Program does its best to minimize interruptions to clinics as much as possible, these visits may occur at any time during the clinic's normal business hours. If a VFC Provider Relations Representative is refused, the clinic will automatically be marked non-compliant, placed on vaccine order hold, and face possible dismissal from the VFC Program.

Follow-Up Site Visits
Additional follow-up site visits may be necessary depending on the results of the compliance or unannounced storage and handling visit.

IQIP Visits
Immunization Quality Improvement for Providers (IQIP) visits are conducted at approximately 25% of enrolled provider sites each year. These visits allow the Utah Immunization Program an opportunity to provide clinics with their personalized immunization rates, discuss quality improvement strategies, celebrate successes, and set goals for improvement. IQIP visits are always scheduled ahead of time with the clinic

- The initial IQIP visit includes generating a Childhood and Adolescent immunization report through USIIS. Assessment reports are reviewed and quality improvement strategies are established in a Strategy Implementation Plan (SIP).
- A 2 month and 6 month check in are completed by phone or email to review synopses and notes from site visit. Identify barriers and provide technical assistance.

- A final 12 month follow up is completed. Assessment reports are generated again. High level summary sent to the provider including strategies, coverage levels, and final SIP. Continued efforts are encouraged.

IQIP visits will receive two follow-up phone calls and a final 12 month follow up phone call. A site visit may be requested by the clinic.

2-2.5 Training Modules

VFC Primary and Back-up Coordinators are required to complete the following training modules:

- New Contact Training (in-person, once)
- You Call the Shots: Module 10: Vaccine Storage and Handling (online, annually, due April 1)
- You Call the Shots: Module 16: VFC (online, annually, due April 1)
- VFC VOMS Ordering Process (online, once)
- VFC Returns and Waste Training (online, once)

New Contact Training

New Primary and Back-up Coordinators are required to participate in an in-person training meeting with a VFC Provider Relations Representative. This training will be scheduled prior to the visit. Training includes the following topics:

- VFC Eligibility and Screening
- Required Documentation
- Storage and Handling
- Inventory Management and Ordering
- USIIS Utilization
- Other Utah-specific VFC Requirements

You Call the Shots

All Primary and Back-up VFC Coordinators are required to complete two online modules on an annual basis. Currently, the Utah VFC Program utilizes the CDC's You Call the Shots modules to fulfill this requirement; these are updated every January. Once the updated modules have been released, the Utah VFC Program sends an email to members of the VFC list serv with links and instructions for completing the training.

The current modules are:

- You Call the Shots: Module 10: Vaccine Storage and Handling
- You Call the Shots: Module 16: VFC

Upon successful completion of each module, the Coordinator will be able to print a certificate, which must then be sent to the provider's assigned VFC Provider Relations Representative.

NOTE: Coordinators can only attempt to take the posttest to receive a valid certificate for these modules twice. If they are unable to pass, more training will be required.

All new Coordinators will receive training instructions from their VFC Provider Relations Representative prior to their New Contact Training site visit.

VOMS Training
Prior to receiving access to order through VOMS, Coordinators must complete two online modules:

- VOMS Ordering Process
- Return and Waste Training

The most current version of each VOMS training module is posted on the Immunization Program Forms website.

Upon successful completion of each module, the Coordinator will be able to print a certificate, which must then be sent to the provider's assigned VFC Provider Relations Representative or to the Vaccine Management Team (see Section 1-2).

2-2.6 Billing

In order to prevent misuse, clinic billing staff must have access to the results of eligibility screening for every immunization patient.

Vaccine supplied by the VFC Program is offered to providers free of charge. Providers may never bill recipients for the cost of the vaccine, but may bill an administration fee which is set by the CMS.

The current cap for a VFC administration fee in Utah is **$20.72** per vaccine.* Clinics may charge anything up to this amount, but may administer VFC vaccine for less or free if desired.

Effective January 1, 2020, providers may issue only a single bill after the date of service for the vaccine administration fee to a non-Medicaid, VFC-eligible child within 90 days of vaccine administration.

NOTE: If a patient/parent/guardian communicates that he or she is unable to pay the administration fee, VFC vaccine must be administered and the administrative fee waived. Patients may never be sent to collections for an inability to pay the administration fee.

*For non-Medicaid patients only. Medicaid sets its own reimbursement rate that may not equate to the maximum administration fee rate allowable.

2-2.7 Withdrawal or Termination

The Utah VFC Program or the provider may terminate the VFC agreement at any time. If the agreement is terminated, the provider must work with the VFC Program to return any unused vaccine within 30 days of termination or withdrawal from the program. Termination to the

program may happen due to failure to comply with program requirements, including but not limited to the following:

- Non-compliance with any VFC Program requirement
- Failure to remedy any compliance issue
- Failure to submit annual provider agreement (see Section 2-2.2)
- Fraud or abuse involving VFC-supplied vaccines
- Administration of non-viable vaccines
- Inadequate vaccine storage equipment or storage practices
- Inability to account for VFC-supplied vaccines
- Vaccine loss due to negligence
- Transfer of VFC-supplied vaccine to non-VFC providers
- Refusal/non-response to requests for VFC site visits or follow-up from Utah Health Department Staff
- Failure to order VFC vaccines within the last twelve months

A provider who withdraws from the VFC Program and terminates their VFC Provider Agreement remains responsible for vaccine doses that expired or spoiled due to negligence or could not be accounted for during VFC Program participation. In such situations, requests for termination might result in delays or the provider could be subject to additional program actions.

Minimally, a provider who withdraws from the VFC Program and terminates their VFC "Provider Agreement" is:

- responsible for every dose of VFC-supplied vaccine in their inventory
- required to store vaccines properly until they can be picked up by a VFC Field Representative or transferred to another VFC provider

VACCINE ORDERING AND INVENTORY MANAGEMENT

Providers enrolled in the Utah VFC Program must appropriately store and manage all publicly-funded vaccines in a manner that avoids cold-chain failure and maintains vaccine viability. Additionally, enrolled providers must also account for all publicly-funded vaccines received by complying with all requirements for vaccine ordering, doses administered documentation and submission, and vaccine control in an effort that avoids fraud, abuse and waste.

Storage and handling responsibilities include:

- Designating Primary and Back-up Coordinators.
- Storage and Handling training (see Section 2-2.5).
- Maintaining a Vaccine Management Plan outlining standard operating as well as emergency procedures (see Section 2-2.3).
- Completing unit certification (including number and type of units storing VFC vaccine).
- Designating shipping hours.
- Safeguarding vaccines.

3-1 Vaccine Storage Units and Equipment

3-1.1 Unit Specifications

VFC-enrolled clinics must provide their own units for storing VFC vaccine.

- Acceptable:
    - Purpose-built (pharmaceutical-grade) stand-alone
    - Purpose-built (pharmaceutical-grade) combination units
    - Freezer-less household or consumer-grade stand-alone units

- Prohibited:
    - Dual-zone (combination) household units
    - Dormitory or bar-style units

Units storing VFC vaccine should be large enough to hold the clinic's highest inventory supply, including back-to-school and flu season. The CDC recommends that units be large enough to hold one year's worth of vaccine stock at once.

Units that will store VFC vaccine must be monitored using a continuous temperature monitoring device (digital data logger). See Section 3-1 2 for more information.

Unit Changes

Providers are required to inform the VFC Program if they change, add, or remove units that will store VFC vaccine.

Do Not Disconnect Warning Stickers

Units that store VFC vaccine must be labeled (either on wall at the power source or on the unit itself) with Do Not Disconnect warning stickers. These stickers must also be placed on the circuit breaker controlling the VFC storage units.

3-1.2 Temperature Monitoring

Continuous Temperature Monitoring Devices (Digital Data Loggers)
As of January 1, 2018, continuous temperature monitoring devices (digital data loggers) are required to monitor all units storing VFC vaccine. Thermometers without data logging capability are not allowed at any time. Obtaining data monitoring probes and software is the responsibility of the provider. All data loggers must include the following features:

- Detachable temperature probe
  - To be kept in buffered medium or material
  - Placed in center of unit away from coils, air vents, or walls
- Continuous temperature monitoring and recording capabilities and the capacity to routinely download data
  - At least one reading every 20 minutes
- Active temperature display external to the unit
  - Ability to read without opening the unit door
  - Last measured temperature displayed in C or F
  - Current, minimum, and maximum temperatures displayed in C or F

Additional recommended features include:

- Alarm function for out-of-range temperatures
- Indicator or notification of low battery
- Accuracy of +/– 1ºF (+/-0.5ºC)

Certificates of Calibration
Continuous temperature monitoring devices (digital data loggers) on VFC units must be accompanied with a current certificate of calibration. It is the responsibility of the provider to maintain and monitor the certificates of calibration and request new probes prior to the expiration dates. Devices without a current certificate of calibration may not be used for VFC units at any time, including during emergency transport. Certificates of calibration testing must include:

- Model/device number
- Serial number
- Date of calibration
- Confirmation that the instrument is in tolerance (passed testing)

Back-up Digital Data Logger
VFC Providers are required to maintain one back-up continuous temperature monitoring device (digital data logger) onsite at all times in the event of an emergency. This digital data logger must be kept separate from the unit and may only be used if vaccine is required to be relocated due to power outage, unit failure, or other temperature excursion, as well as malfunction of a regular continuous temperature monitoring device. It is the responsibility of the provider to purchase and maintain the back-up digital data logger, including its certificate of calibration.

Thermometers without data-logging capability are not allowed and may not be used as back-up thermometers.

Back-up thermometers must be accompanied by a current certificate of calibration. It is the provider's responsibility to maintain and monitor this certificate and request a new probe prior to the expiration date.

Temperature Ranges
Acceptable temperatures are:

- Refrigerated Vaccine: 2.0º - 8.0º C (36.0º – 46.0º F)
- Frozen Vaccine: -50.0º C to -15.0º C (-58.0º to +5.0º F)

Temperature Documentation
As of January 1, 2018, all temperature documentation must be reported via the use of a continuous temperature monitoring device. Providers are required to record the minimum/maximum (min/max) temperature reading once per day at the time the facility opens. The min/max reading will record the highest and lowest temperatures the unit reached since the last recording was taken. This will take the place of twice daily temperature recordings from previous years.

Documented information for each recording must include:

- Clinic Name
- VFC Pin
- USIIS ID
- Unit Name
- Date
- Time
- Minimum Temperature
- Maximum Temperature
- Staff Initials
- Troubleshoot Record or similar (if min/max is out of range)

Temperature logs can be found here (Celsius), and here (Fahrenheit).

If the digital data logger does not record all required information, manual temperature logs must be maintained to satisfy this requirement. Use of a digital data logger by itself does not meet the once daily minimum/maximum temperature requirement. Use of a manual temperature log does not negate the requirement to physically review all temperature recordings since last min/max review.

3-2 Vaccine Storage

Always store vaccine in a temperature-stable location of the storage unit:

- Store vaccines in middle of refrigerator or freezer unit away from coils, walls, floor and cold air vents.
- At least two-three inches away from the walls, floor, and ceiling of the storage compartment.
- Never store vaccines in door, vegetable bins, on floor of the unit, or adjacent to cooling vents.

- Stabilize refrigerator and freezer temperatures with proper placement of water bottles in refrigerator; frozen packs in freezer (unless otherwise stated in unit manufacturer instructions).
- Avoid over-filling refrigerator and hindering air circulation.
- Do not store food or drink in vaccine storage units.
- Provide enough space to store vaccine for extended timeframe.
- Public and private stock should be clearly separated with stickers or another method to ensure proper vaccine selection.
- Store vaccine in the original packaging.
- If needed, place vaccine designated storage trays in the center of the unit. These units must not be enclosed and must allow for adequate air flow.

3-3 Temperature Excursions

Beginning January 1, 2019, providers must take action for every temperature outside manufacturer temperature ranges, regardless of length of time. Action must include documentation of response, manufacturer case numbers, vaccine viability and plan of action to prevent future temperature excursions, by submitting documentation to the assigned Provider Relations Representative and the Vaccine Management team.

Vaccine Potency

All vaccines are sensitive biological substances that progressively lose their potency over time or when exposed to harmful temperatures and/or light.

- Loss of potency is cumulative unless vaccine is frozen, in which case, spoilage may occur instantly.
- Once potency is lost, it can never be restored, even if vaccine is returned to the correct temperature range.

Any time temperatures are recorded outside of manufacturer temperature ranges, providers must take action to evaluate the situation and verify vaccine viability.

Spoilage Protocol

In the event of a power outage, unit malfunction, or temperature excursion, providers should:

- Take action immediately and identify the issue.
- Implement Vaccine Management Plan and relocate the vaccine to a unit with proper temperature conditions (onsite or at back-up clinic).
  - Transfer vaccine using insulated container and certified data logger (see Section 3-5.4).
- Mark the vaccine DO NOT USE.
- Document the current temperature and time interval of the outage.
- Notify the VFC Program of the potential spoilage.
- Contact each vaccine manufacturer to verify the viability of the products (manufacturer contact information may be found on the Emergency Response Checklist).
- Notify the VFC Program with the results by providing the following information on Troubleshooting Record (or similar):

  - Vaccine viability by product and lot, including date contacted, representative name, outcome, and case number (if assigned).
  - Incident report documenting reason for vaccine exposure to temperatures outside acceptable range.
  - Plan of action for preventing similar incidents in the future.
  - Temperature logs for one week following the incident.
- Providers should never attempt to return vaccine to original units without instructions from their VFC Provider Relations Representative.

Note: Vaccine exposure times are cumulative. For example, if a unit is out of range for 10 minutes one day and 10 minutes the following day, the vaccine inside has now been exposed to out of range temperatures for 20 minutes. See Calculating Temperature Excursions below for instructions.

Calculating Temperature Excursions
As of January 1, 2018, all thermometers are required to include data logging technology, which will provide more accurate temperature excursion time. Excursion time is defined as the last recorded in-range temperature prior to the excursion to the first in-range temperature post-excursion (or the time the vaccine was moved into an in-range environment/unit).

If digital data logger does not yield sufficient information, calculate current exposure time using time between last recorded in-range temperature to first recorded in-range temperature (see Section 3-1.2):

- Identify highest or lowest temperature reached.
- If vaccine has been exposed before, add time from previous excursion(s) to current excursion timeline.
- Calculate total duration by adding current duration and previous exposure time.
- Identify worst case temperature as the highest/lowest and/or temperature reached, including the current excursion and any previous excursions.
- Use a certified, calibrated thermometer to determine if units are currently in range.

3-4 Vaccine Ordering

3-4.1 Ordering Schedule

Upon enrollment, an ordering schedule will be assigned, indicating how often a clinic may order VFC vaccine. This schedule is determined by the information reported in the Provider Profile section of the Enrollment Agreement. The most common ordering schedules are monthly, bi-monthly, and quarterly.

If changes occur to a clinic's patient population, providers should fill out and submit a Provider Profile Adjustment form, which can be found here.

3-4.2 Vaccine Order Management System (VOMS)

VFC vaccine orders must be submitted online through the Vaccine Order Management System (VOMS). This program may be accessed in USIIS once a VFC coordinator or back-up coordinator has participated in the required online training modules (see Section 2-2.5) and submitted certificates of completion to the Utah VFC Program. To submit an order, the Primary or Back-up Coordinator must be an active user in USIIS (see Section 2-2.3).

Submitting Orders

All orders must be submitted through VOMS. All orders must include temperature documentation for the past 30 days prior to order submission and documentation of current inventory.

Temperature logs must be emailed and received prior to order submission. Once temperature documentation has been approved by the VFC Program, the order may be completed in VOMS.

Beginning with the 2018-19 season, influenza vaccine will be pre-booked through VOMS. Influenza vaccine distribution will begin automatically once vaccine is allocated to the Utah VFC Program.

For a detailed tutorial for using the VOMS system, please review the VOMS training modules (see Section 2-2.5).

Brand Choice Policy

The Utah VFC Program provides all ACIP-recommended vaccines and allows providers to select which brands and/or presentation they prefer. In the event that a preferred brand or presentation is not available, orders will be filled with an alternate.

Due to lack of VFC provider uptake/usage or limited use, select vaccines will only be available upon special request. These vaccines include:

- DT
- Td
- PPV23

Pneumococcal Polysaccharide Vaccine (PPV23) is available by special request from the Utah VFC Program for uninsured, American Indian/Alaska Native, and underinsured (in an FQHC/RHC) only. Providers that carry PPV23 in their private stock should vaccinate Medicaid or CHIP children and request reimbursement from Medicaid/CHIP in order to avoid missed opportunities to vaccinate. Providers that do not carry PPV23 in their private stock may request doses from the Utah VFC Program for their Medicaid or CHIP patients.

3-4.3 Shipping and Delivery

Vaccine shipping hours are determined by the clinic during annual re-enrollment on the Provider Agreement form. Clinics are required to list at least one four-hour block on a non-Monday. Any time the clinic will be closed (i.e., lunch hours) should be accounted for.

If any vaccines are delivered outside of these designated shipping hours, please contact the Utah VFC Program immediately. Vaccine shipment should always be accepted, even when vaccine viability is questioned. If there are any questions about viability, please contact the Utah VFC Program immediately.
The following are recommended steps for receiving VFC vaccine:

- Open package immediately.
- Review contents with packing slip. Verify packing slip matches product box.
- Store under proper temperatures immediately.
- Verify temperature monitors in box as well as total shipping time (should be less than 48 hours).
- Notify Utah VFC Program of any discrepancies within two hours of delivery.

When reporting a discrepancy to Vaccine Management, send an email to vacteam@utah.gov with a copy of the packing slip and notation of discrepancy, FedEx/UPS tracking number, date shipped, and shipping label.

Merck vaccines should always be delivered within 48 hours of shipping. If delivery is after 48 hours, please contact Vaccine Management within two hours of receipt. If Vaccine Management is unavailable, Merck should be contacted to verify vaccine viability and an email should be sent to vacteam@utah.gov to notify the VFC Program.

3-5 Inventory Management and Vaccine Accountability

Enrolled providers must account for all publicly-funded vaccines received by complying with all requirements for vaccine ordering, doses administered submission, and vaccine management in a way that avoids fraud, abuse, and waste.

It is required that providers complete a monthly inventory, and highly recommended that they perform a monthly reconciliation (or more often as necessary) of all public vaccine stock. Missing doses should always be reported to the Utah VFC Program.

Doses Administered

Enrolled providers are required to submit doses administered data to the online Doses Administered Reporting system in USIIS. Doses must be tracked and reported by eligibility status, vaccine, and age group.

Doses Administered Reports (DAR) should indicate appropriate screening and reflect accurate, appropriate usage of publicly-funded vaccine during each quarter. Providers are required to submit patient data for all VFC vaccine administered to USIIS within 14 days. Failure to account for all vaccine doses will affect DAR as well as allowable doses per order, and may result in request of dose-for-dose replacement and/or referral to Medicaid Program Integrity (see Section 3-5.6).

Doses Administered Reports are due the 15th of the month after the quarter has ended (see Section 2-2.3). Failure to submit two or more quarters will result in a vaccine ordering hold.

3-5.1 Monthly Inventory

Enrolled providers are required to conduct a monthly physical inventory of vaccines and/or reconcile USIIS inventory. Depending on the clinic, more frequent inventory counts may be necessary to prevent vaccine loss. Monthly inventory documentation must be archived onsite for a period of seven years.
Providers must submit a current inventory (taken within the last seven days) with each order. This may only be submitted through the VOMS Current Inventory page and should accurately reflect the clinic's current inventory in USIIS. Simply updating the USIIS inventory module does not satisfy this requirement.

Inventory reports should include:

- Brand name
- Manufacturer
- Lot number*
- Expiration*
- National Drug Code (NDC)*
- Number of doses

*Information should be recorded from the original packaging, as vials and syringes may contain different information.

A blank inventory sheet may be found here.

3-5.2 Administration and Stock Rotation

For all vaccines identified and agreed upon in the provider profile, VFC-enrolled providers must comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC Program unless:

- In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
- The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

The ACIP recommendations may be located on the CDC's ACIP index page.

Pre-Drawing Vaccine

Vaccine may never be pre-drawn for administration. If vaccine is drawn and not used, it must be discarded at the end of the clinic day and documented as a waste (see Section 3-5.3). The only exception is reconstituted vaccine, which must be discarded after 30 minutes and documented as a waste.

Multi-dose vials are valid until the date printed on the vial unless otherwise stated in the package insert. Multi-dose vials should only be entered 10 times. If vaccine remains after 10 doses, the rest should be discarded and does not need to be reported as waste.

Stock Rotation
VFC vaccine stock should be rotated so that the doses closest to expiring will be used first.

3-5.3 Returns, Waste, and Spoilage

Expired Returns
For accountability, providers must complete a return request in VOMS within 30 days of expiration.

The Utah VFC Program will process the return request, email the Return Authorization (RA), and request an email UPS label from McKesson. Labels should arrive within 24 hours to the primary contact's email. If a label is not received, providers must contact the Utah VFC Program and a new request will be made.

Return vaccine may be packaged in any box or padded envelope and does not need to be kept at any particular temperature. A copy of the RA should be included with the package. Returns should never include:

- Open multi-dose vials (these should be reported as Wasted/Destroyed and discarded)
- Pre-filled syringes not originally packaged by the manufacturer (pre-drawn doses should be reported as Wasted/Destroyed and discarded)
- Needles

The UPS label should be attached to the outside of the package with all information visible. Provider's UPS carrier should accept all return packages but in the event that a package is refused, provider should contact the Utah VFC Program to schedule a pick-up.

Wasted Vaccine
For accountability, providers must complete a waste request in VOMS within 30 days of wastage.

Vaccine is considered wasted when it has not been exposed to out of range temperatures but is otherwise unusable. Examples include breaking a syringe, dropping and breaking a vial, or spilling part of a dose. It may also include vaccine that is requested and drawn up but is not administered due to the patient or parent changing his/her mind. Open multi-dose vials (MDV) that expire or are deemed non-viable due to spoilage are also considered waste.

All wasted vaccine must be reported to the Utah VFC Program through VOMS (see Section 3-4.2). Upon notification of a wasted vaccine, the Utah VFC Program will send a waste authorization via email to the contact that reported the waste. Once the waste authorization has been received, the provider is allowed to discard the vaccine. Providers should always keep a copy of the waste authorization for their records.

Spoiled Vaccine
Vaccine is considered spoiled when it has been exposed to out of range temperatures and has been deemed unusable by the manufacturer. Power outages, unit failures, and leaving vaccine out can cause vaccine to spoil.

All spoiled vaccine must be reported to the Utah VFC Program through VOMS (see Section 3-4.2). Upon notification of a potential spoilage, provider will be placed on vaccine order hold (suspended status) until all documentation and corrective action has been received by the VFC Program.

Note: All designated reasons for spoilage require an incident report, manufacturer viability report, temperature logs, and a plan of action. The information must be received in addition to the return request in VOMS.

3-5.4 Transfers

Providers are responsible for all VFC vaccine received. Providers are required to notify the Utah VFC Program of all vaccines that will expire within 90 days of expiration. Vaccine transfers without prior approval of the Utah VFC Program are not allowed except when activating an emergency response plan. If vaccine is lost due to expiration, waste or spoilage, the provider may be held responsible to replace the lost doses.

Request for Transfers

Providers should email a Vaccine Transfer Form to Vaccine Management (vacteam@utah.gov) 90 days prior to expiration of all vaccine stock. Transfer requests will be reviewed on a case-by-case basis to determine cost-effectiveness.

Based on manufacturer and CDC guidance, vaccine products may not be transported without an approved portable fridge/freezer or certified pack-out and a calibrated data logger. Due to limited supply of approved pack-outs, transfer requests may or may not be approved. Providers should still submit a request to transfer 90 days prior to expiration.

If approved, the Utah VFC Program will dispatch a VFC Provider Relations Representative or other staff member to complete the transfer.

Emergency Transport

During a power outage, unit failure, or other emergency situation, providers should follow their Vaccine Management Plan and activate emergency relocation plans to transport vaccine using cold packs and an insulated container. Vaccine must be transferred with a certified, calibrated digital data logger that documents temperature at least once every five minutes.

Please review the CDC Handout for Emergency Transport for emergency transportation protocols.

NOTE: In an emergency, frozen vaccine may transported in the same carrier as refrigerated vaccine, but this information must be reported when contacting manufacturers to determine viability after transfer has been completed.

3-5.5 Misuse and Borrowing

Borrowing Policy
The Utah VFC Program does not allow borrowing and/or replacement of doses between vaccine supplies under any circumstance.

Administration of any publicly supplied vaccine to a non-eligible patient is not allowed. In addition, replacement of a provider's private vaccine supply with any publicly supplied vaccine is not allowed.

Vaccine borrowing includes intentional or accidental administration of any publicly supplied vaccine to a patient who does not meet eligibility requirements with the intent of replacing from the provider's private vaccine supply.

Providers must maintain separate vaccine inventory for publicly and privately purchased supplies.

Misuse of VFC Vaccine
If vaccine misuse occurs intentionally or accidentally, the provider is required to notify the Utah VFC Program immediately after discovering the incident. The following information must be submitted within five business days of discovery:

Misuse Report Template:
Misuse reports must include the following information:

- Clinic Name, VFC PIN, USIIS ID
- Name of person completing report
- Patient Information:
  - Patient Identifier
  - Insurance Status
  - Date of Birth
  - Date vaccinated
- Vaccine Information
- Vaccine(s) used
- Manufacturer
- Lot Number
- NDC
- Expiration Date
- Reason for use of wrong vaccine supply
- Plan of action to prevent future misuse

The Utah VFC Program may request reimbursement for the dose(s) misused. Other possible outcomes include referral to Medicaid Program Integrity and removal from the VFC Program.

Incident Report for misuse should be submitted to the Utah VFC Program by secure email or fax (see Section 1-2).

3-5.6 Restitution

VFC providers are responsible for the oversight and management of all publicly-funded vaccines received by their facilities; ensuring proper storage, administration to eligible populations, accountability and inventory management to avoid preventable vaccine loss. VFC providers must comply with all Vaccine Management requirements for vaccine storage, handling, and accountability in an effort that avoids fraud, abuse, and waste. Upon signing the VFC Provider Profile and Enrollment Agreement, the provider agrees to replace vaccine loss on a dose-per-dose basis.

Provider Responsibility

- Monitor vaccine inventory through appropriate stock rotation and vaccine ordering while maintaining acceptable temperatures, as defined by Vaccine Management policy (see Section 3-1.2).
- Conduct full vaccine inventories monthly to identify any missing doses or product that will expire in the next 90 days, as defined in the Vaccine Management policy (see Section 3-5.4). Providers should notify the Utah VFC Program of any product that expires in the next 90 days and request vaccine transfer assistance, as they may be held financially responsible if product expires.
- Submit quarterly doses administered reports timely and accurately.
- Maintain written policies for routine and emergency storage and handling, including back-up storage plans with another clinic/hospital facility.
- Place responsible orders that allow for utilization of all vaccine in inventory before expiration. Clinic may be billed for expired vaccine.
- Notify the Utah VFC Program of all vaccine loss due to spoilage, waste, or expiration, by the appropriate submission in VOMS.

Note: If spoilage occurs due to negligence, provider may be held responsible for replacing the spoiled vaccine dose-for-dose.

ADDITIONAL RESOURCES

Advisory Committee on Immunization Practices (ACIP)

Billing Scenarios

CDC Handout for Emergency Transport

CDC Immunization Schedules

CDC Pink Book (Epidemiology and Prevention of Vaccine-Preventable Diseases)

CDC Storage and Handling Toolkit

CDC Vaccine Administration Guidelines

CDC Vaccines Home

Utah Division of Occupational and Professional Licensing (DOPL)

Utah Immunization Program (UIP)

Utah VFC Provider Forms and Training Materials

National Childhood Vaccine Injury Act (NCVIA)

USIIS

Vaccine Adverse Event Reporting System (VAERS)

Vaccine Information Statements (VIS)

Vaccine Order Management System (VOMS) Training

VFC Eligible Flyer

VFC Funding Policy

VFC Provider Requirements

You Call the Shots Training Modules

Utah Department of Health
Immunization Program
P.O. Box 142012
Salt Lake City, UT 84114
PH 801-538-9450
FAX 801-538-9440